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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/284,858 | 04/21/1999 | ISAAC GHEBRE-SELLASSIE | 5741-01-EJF | 2903 |

7590

04/16/2002

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284858

Applicant(s)

GIBERLE-SELAJIS

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 12/17/01

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-7, 10 is/are pending in the application.

Of the above claim(s) is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-7, 10 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claim(s) are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5,-7, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al.

Tanaka et al. teach drugs coated with synthetic cellulose ethers and vinyl polymers (claims 1-3). Hydroxy propyl cellulose, hydroxypropylmethyl cellulose and polyvinyl pyrrolidone are disclosed (column 3 lines 55-60). Nifedipine is specified (column 2 line 48). Prolonged release is disclosed. Any particulate medicinal is recited (column 2 lines 46-47).

Applicants argue that Tanaka et al teach water insoluble polymers, however, column 3, line 53 clearly discloses water-soluble polymers, including, as recited above, applicant's claimed polymers. As to the claimed crystalline compound, the examiner takes notice under MPEP 2144.03 that Nifedipine is a crystalline substance. As to applicant's argued properties, they must be possessed by the anticipatory composition, because it is the same as that claimed.

As to applicant's argument concerning methods of making, it is argued that the Tanaka composition is the same as the claimed composition.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olefsky et al in view of Tanaka et al.

Olefsky et al. teach troglitazone and rosiglitazone (column 26 lines 57-59, column 28 lines 10-11). Solid form preparations are specified (column 16 lines 55-60).

Tanaka et al is discussed above.

It would have been obvious to one of ordinary skill to deliver the compounds of Olefsky et al with the vehicle of Tanaka et al to achieve the beneficial effect of delayed release.

Applicant argues that Olefsky et al not teach applicants' method of making. However, it is argued that the obvious combination is the same as applicants' claimed composition.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR

March 29, 2002


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500